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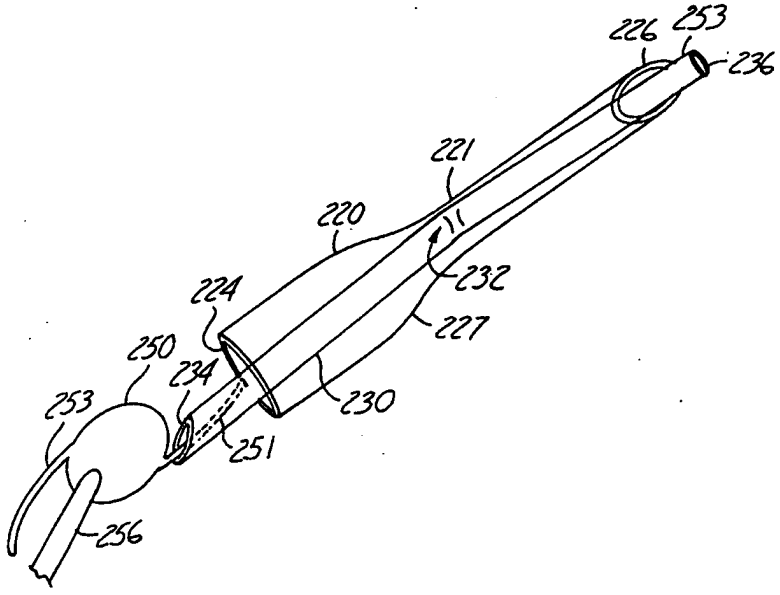
(54) Title: MOBILE GUIDE FOR AN OPHTHALMOLOGIC INSERTOR APPARATUS AND METHODS OF USE

(57) Abstract

An apparatus for protecting an implantable lens is disclosed. The apparatus includes a movable guide or brace that protects an implantable lens as the lens is loaded into an insertor device. The guide is removed from the insertor device after loading of the lens and prior to inserting the lens into the eye. The guide includes an elongated structure having an inner periphery sufficient in size to receive a support or haptic of the lens. The guide has a relatively thin wall and a stiffness sufficient to partially straighten the lens support. The guide protects a leading support from unintended distortion or misalignment as the lens is loaded into the insertor device. A guide may also be used to protect a trailing support of the lens. A resilient sleeve adapted for use in an insertor device may be used in combination with the guide. The sleeve includes a first opening and a second opening with a lumen extending therethrough. The guide has an inner periphery sufficiently large to receive a support of the lens, and an outer periphery sufficiently small to permit the guide to pass through the first and second sleeve openings. A stop mechanism may be provided on the guide, the sleeve, or both the guide and sleeve to prevent unintended slippage between the guide and sleeve during use. The guide is typically fabricated from a non–opaque material, and, when used in combination with a sleeve, both the guide and sleeve may be fabricated from the same or similar material.



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MOBILE GUIDE FOR AN OPHTHALMOLOGIC INSERTOR APPARATUS AND METHODS OF USE

Cross-Related Applications

This is a continuation-in-part of U.S. Patent Application Serial No. 09/061,652 filed 17 April 1998, which is a continuation-in-part of U.S. Patent Application Serial No. 08/956,987, filed 24 October 1997, both of which are incorporated herein by reference.

Field of the Invention

The present invention relates to the field of ophthalmology and to the use of medical devices in ophthalmologic surgery. More particularly, the present invention relates to an apparatus and method for guiding an implantable lens into the eye.

Background of the Invention

Artificial intraocular lenses are widely used to replace the human crystalline lens of the eye. The human crystalline lens is a living transparent structure composed primarily of protein having a thickness of about five millimeters and a diameter of about nine millimeters. The lens is suspended behind the iris by zonula fibers that connect the lens to the ciliary body. A lens capsule surrounds the lens. The front portion of the capsule is generally referred to as the anterior capsule and the back portion is generally referred to as the posterior capsule.

The term "cataract" refers to the opacity of the lens of the eye. There are a variety of types of cataracts and for most cataracts, surgical intervention is required to remove and replace the lens with an artificial intraocular lens.

The transparency of the lens depends on the physiochemical state of the lens proteins. These proteins, like the proteins of other organs, are sensitive to changes in the properties of their surrounding fluid. Changes in the concentration of dissolved salts, in the pH, in the enzyme activity, or in the osmotic pressure of the surrounding fluid can alter the properties of the lens proteins. Also, like other organs, changes to the proteins of the lens occur with age. A common type of cataract that occurs in elderly people, for example, is known as a senile cataract. This type of cataract has no known etiology and none of the forms of cataracts produced experimentally to date closely resemble the senile cataract.

Artificial intraocular lenses generally comprise an optical region and a support, or haptic, to facilitate positioning and centering of the intraocular lens within the eye. Intraocular lenses have been made from a number of different materials. For example, hard lenses have been prepared from polymethylmethacrylate (PMMA) and optical glass while flexible lenses have been prepared from silicone, polyHEMA (polyhydroxyethylmethymethacrylate), acrylics, collagen, and combinations thereof. Flexible lenses have the advantage that they can be folded or otherwise deformed prior to implantation to reduce the overall size of the lens during the artificial lens implantation procedure.

There are a number of procedures and devices that have been developed for the removal of the natural lens followed by the insertion of an artificial lens. The extraction procedure can generally be categorized as intracapsular (i.e., where the lens is removed together with the lens capsule) or extracapsular (such as where a portion of the anterior capsule is circularly removed (capsulorhexis) and the posterior capsule is left intact).

Presently, phacoemulsification is a widely used method for the removal of diseased or damaged natural lens tissue. The phacoemulsification process generally employs a small incision typically of about 2 millimeters (mm) to about 4 mm in length (but potentially as small as 1 mm) through the cornea and a probe is used to ultrasonically break apart and remove the crystalline lens through the capsulorhexis.

There are a number of intraocular lens injectors that have been described in the literature to position a deformable artificial intraocular lens in the eye. These injectors typically use an incision of about 2 mm to about 4 mm, which represents the incision size most frequently used in most phacoemulsification procedures. A larger (about 4 mm to about 5 mm) capsulorhexis incision, also used in phacoemulsification procedures, is used to position the lens without requiring elongation of the incision during the injection process.

A problem well appreciated by physicians and others skilled in the art concerns unintended deformation and/or misalignment of an intraocular lens that often occurs as the lens is loaded into an injection or insertor device. By way of example, the leading haptic of an intraocular lens is particularly susceptible to bending or kinking as it is advanced into and through the insertor device. More particularly, the leading haptic may engage an obstruction, such as a constricting portion a containment chamber or passageway of the insertor device during loading of the intraocular lens, causing varying degrees of kinking or misalignment. Further, the trailing haptic may also be damaged by the lens manipulating mechanism of the insertor device or by forceps used by the physician. The resulting unintended alteration in configuration or orientation of a leading or trailing haptic may render the intraocular lens assembly unusable.

A number of injector devices have been developed that purportedly provide features that enhance the process of implanting an intraocular lens into the eye. Examples of such devices are disclosed in U.S. Pat. Nos. 4,681,102 to Bartell; 4,702,244 and 4,573,998 to Mazzocco; 5,468,246 to Blake; 5,562,676 to

Brady; 5,275,604 to Rheinish; 5,474,562 to Orchowski; 4,919,150 to Stoy; 5,123,905 to Kelman; 5,616,148 to Eagles; and 5,496,328 to Nakajima. In general, these injector devices include a mechanism that manipulates a soft intraocular lens into a shape and orientation appropriate for insertion into the eye, such as by folding or otherwise compressing the intraocular lens into a shape having a smaller cross-sectional area than the original unfolded cross-sectional dimension of the lens. These devices can damage the lens and a supporting haptic, such as by tearing the lens or kinking a haptic, during the deformation process if the lens is not accurately and carefully positioned in the device. Moreover, many of these devices employ a plunger or push-rod to apply a force on a lens and to push the deformed lens from the device into the eye. If the lens is not properly and accurately positioned within the device prior to activating the plunger, the pushing action of the plunger can damage the lens material and haptics before the lens is positioned in the eye.

There remains a need for a device for introducing a flexible lens implant, particularly a fragile foldable lens, into the eye without damaging the lens implant. In particular, there is a need for a device to implant a foldable intraocular lens into the eye without damaging a haptic or the lens during the implantation process. The present invention fulfills these and other needs.

Summary Of The Invention

The present invention is directed to an apparatus for protecting an implantable lens as the lens is loaded into an insertor device. The apparatus includes a guide or brace that moves with the implantable lens and supports the lens as it is loaded into the insertor device. The guide is removed from the insertor device after loading of the lens and prior to inserting the lens into the eye. The guide includes an elongated structure, such as a tube or channeled

structure, having an inner diameter sufficient in size to receive a support, such as a leading haptic, of the lens. The guide protects the leading support from unintended distortion or misalignment as the lens is loaded into the insertor device. A guide may also be used to protect a support other than the leading support, such as a trailing support of the lens.

In one embodiment, the guide is used in combination with a resilient sleeve adapted for use in an insertor device. The sleeve includes a first opening and a second opening with a lumen extending through the sleeve. The size of the first opening is greater than the size of the second opening, and the thickness of a wall of the first opening is thinner than the thickness of a wall of the second opening. The guide has an inner diameter or periphery that is sufficiently large to receive a support of an intraocular lens, and an outer diameter or periphery that is sufficiently small to permit the guide to pass through the first and second openings of the sleeve. A stop mechanism may be provided on the guide, the sleeve, or both the guide and sleeve to prevent unintended slippage between the guide and sleeve during use.

The guide has a relatively thin wall and a stiffness that is sufficient to partially straighten a support of an intraocular lens. The wall of the guide typically has a thickness ranging from approximately 0.01 mm to approximately 0.30 mm. The outer diameter of the guide typically ranges from approximately 0.30 mm to approximately 3.0 mm. The ratio of guide wall thickness with respect to the outer diameter of the guide typically ranges from approximately 1:5 to approximately 1:25. In an embodiment that includes the guide in combination with a resilient sleeve, the ratio of the outer diameter of the sleeve with respect to the outer diameter of the guide typically ranges between approximately 1.25 to approximately 10.

The guide is typically fabricated from a non-opaque material and, when used in combination with a sleeve, both the guide and sleeve are fabricated from a non-opaque material. The guide may alternatively be fabricated from opaque

material. In general, the guide may be fabricated from the same or similar material used to fabricate the sleeve. A polymeric material, such as tubing fabricated from PTFE, ETFE or PFA, for example, may be used to construct the guide and the sleeve.

In accordance with another embodiment, the present invention is directed to a system for loading an intraocular lens into an insertor device. The system includes a resilient sleeve having a first opening, a second opening, and a longitudinal axis. A guide engages a support of the intraocular lens and exerts a force on the support to urge a leading end of the support towards the longitudinal axis of the sleeve. A lens manipulating device is provided to advance the intraocular lens and guide into the first opening of the sleeve. The leading end of the support is protected from damage by the guide, and the guide is separated from the support and removed through the second opening prior to inserting the intraocular lens into an eye using the insertor device.

The invention is also directed to a kit including an intraocular lens and a resilient sleeve having a first opening and a second opening and a lumen extending therethrough, wherein the sleeve is configured to receive the lens. The kit further includes a guide comprising an elongated tube or any other elongated shape having an inner periphery (e.g., diameter) dimensioned to receive a support of the intraocular lens and an outer periphery (e.g., diameter) smaller than a width of the first and second openings of the sleeve. The guide and sleeve of the kit are fabricated from non-opaque material.

The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages and attainments, together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

Brief Description Of The Drawings

Figure 1 is an exploded perspective view of an exemplary lens insertor which employs a mobile guide of the present invention. Figure 1a is a perspective view of a collet, and Figure 1b is a cross-section through the collet at G-G as illustrated in Figure 1.

Figure 2 is an illustration of an intraocular lens being loaded into a sleeve of an insertor device without the use of a mobile guide of the present invention.

Figure 3a is a perspective view of an assembled sleeve, collet, and ring clamp positioned onto a hand-piece employing with a pushrod. Figure 3b is a perspective view of the assembled device of Figure 3a. Figure 3c is a cross-section through lines E-E illustrating the position of the pushrod in the sleeve within the lumen of the collet.

Figure 4 is a perspective view of a preferred sleeve holder of this invention.

Figure 5a is a cross-sectional view of a multi-piece sleeve according to the invention. Figure 5b illustrates a multi-piece sleeve following separation of the sleeve.

Figure 6 is an illustration of a mobile guide of the present invention supporting a haptic of an intraocular lens prior to loading the lens into an insertor device.

Figure 7 illustrates insertion of a haptic of an intraocular lens into a mobile guide of the present invention following insertion of the mobile guide into a sleeve of an insertor device.

Figure 8 illustrates insertion of an intraocular lens into a sleeve of an insertor device, a haptic of the lens being protected by a mobile guide of the present invention.

Figure 9 illustrates removal of a mobile guide of the present invention from a haptic of an intraocular lens after the lens is loaded into the sleeve of an insertor device and prior to inserting the lens into the eye.

Figure 10 is a cross-sectional view of an assembled insertor device according to Figure 1.

Figure 11 is a cross-sectional view of the assembled insertor device of Figure 10 rotated 90°.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail hereinbelow. It is to be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE VARIOUS EMBODIMENTS

In the following description of the illustrated embodiments, references are made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration, various embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilized, and structural and functional changes may be made without departing from the scope of the present invention.

The term "proximal" is used herein to refer to that portion of a device or element of the device that is closest to the physician's finger that is being used to activate the device or element of the device. The term "distal" is used herein to refer to that portion of a device or element of the device that is farthest from the physician's finger that is being used to activate the device or element of the device.

The present invention is directed to an apparatus for preventing damage to an intraocular lens when loading the lens into an insertor device. The present invention is also directed to a device for introducing an intraocular lens into the eye. Referring to the drawings and, more particularly, to Figure 1, there is provided an exploded view of a device for inserting an intraocular lens into the eye of a patient in accordance with an embodiment of the present invention.

The insertor device 10 shown in Figure 1 represents one of a wide variety of insertor devices which may be employed in combination with a mobile guide of the present invention to prevent damage to a haptic of an intraocular lens when the lens is loaded into the insertor device. The insertor device 10, as well as other insertor device embodiments characterized herein, is intended to provide an illustrative environment of use within which the features and advantages of the mobile guide of the present invention may be described and appreciated.

The insertor device 10 includes a hand-piece 12, a pusher element 14 capable of engaging at least one push-blade 16, a collet 18 capable of receiving a compressible sleeve 20, and a ring clamp 22 to secure the collet 18 to hand-piece 12. In general, sleeve 20 protects a lens implant 50 from damage and provides a cost effective delivery system for introducing a lens implant 50 into the eye. The insertor device 10 shown in Figure 1 will be later described in greater detail hereinbelow.

Figure 2 is an illustration showing an intraocular lens 250 being loaded into a sleeve 220 of an insertor device in accordance with a typical insertion approach. It is understood that sleeve 220 is intended to represent any structure for containing an intraocular lens that facilitates delivery of the lens into the eye using an insertor device. Intraocular lens 250 includes a distal or leading haptic 251 and a proximal or trailing haptic 253. In accordance with the embodiment shown in Figure 2, sleeve 220 includes a first opening 224 capable of receiving an intraocular lens 250. The first opening 224 (i.e., the proximal portion of sleeve 220) is shown having a width that is sufficient to receive an unfolded or

substantially unfolded lens 250. The first opening 224 may alternatively be small enough to require some deformation of the lens 250. A pair of forceps 256 or other lens handling device is employed to grasp the intraocular lens 250 and load lens 250 into sleeve 220.

Those skilled in the art well appreciate the difficulty of loading an intraocular lens into a sleeve 220 or other containment structure of an intraocular lens insertor device without distorting the lens in an unintended manner. More particularly, and as illustrated in Figure 2, the distal or leading haptic 251 is susceptible to deleterious bending or kinking as it is advanced into the first opening 224 of the sleeve 220. For example, leading haptic 251 may engage an obstruction within sleeve 220, such as a constricting portion 227 of sleeve 220, during loading of intraocular lens 250 into sleeve 220. The leading haptic 251 may be bent, kinked, or otherwise deformed resulting from imprecise loading of intraocular lens 250 into sleeve 220. Although intraocular lens 250' (shown in phantom) may be situated at the proper location within sleeve 220 after completion of a conventional loading procedure, as is shown in Figure 2, unintended alteration in terms of configuration or orientation of leading haptic 251' may render the intraocular lens/sleeve assembly unusable. Further, undesirable distortion of the leading haptic 251' may altogether preclude proper positioning of the lens 250' within sleeve 220.

Loading an intraocular lens into a lens manipulating chamber or structure of an insertor device, such as sleeve 220, with sufficient precision so as to avoid unintended distortion of the leading haptic 251 is made further difficult by the wide variety of possible sleeve configurations. For example, useful sleeve configurations include those with a tapered portion 227 having any one of the following cross-sectional configurations: a circular cross-section; an elliptical cross-section; a flattened cross-section; an enveloped cross-section; a pleated cross-section; a plurality of pleats in cross-section; and a "V" shaped configuration in cross-section, or a combination thereof. Those skilled in the art

will appreciate that there are a number of other cross-sectional configurations that are possible. It will be further appreciated that the level of difficulty associated with properly loading intraocular lens 250 into sleeve 220 varies depending on the particular sleeve and lens configuration encountered during a surgical procedure.

A guide, in accordance with the principles of the present invention, is advantageously employed to properly guide an intraocular lens so as to prevent damage to the lens when loaded into an insertor device. More particularly, the guide of the present invention prevents unintended bending or kinking of a haptic of the intraocular lens as the lens is loaded into the insertor device. In one embodiment, as is depicted in Figure 6, a guide 230 is used to prevent undesirable deflection of the leading haptic 251 during the process of loading the intraocular lens 250 into sleeve 220 or similar lens manipulating structure of an insertor device. A guide may also be used to prevent unintended distortion of trailing haptic 253 as intraocular lens 220 is loaded into sleeve 220. Guide 230 may be viewed as constituting a mobile guide or brace, since guide 230 is intended to move with intraocular lens 250 as lens 250 is loaded into the insertor device. Guide 230 is removed from the insertor device prior to insertion of the lens 250 into the eye.

Guide 230 is employed to protect and/or guide a securing member or support (e.g., haptic) of an intraocular lens as the lens is loaded into an insertor or injector device. Guide 230 may be particularly useful when used in combination with a novel sleeve of the type described herein, but it is understood that guide 230 may be used in insertor devices that do not employ such a sleeve, such as the devices discussed in the Background of the Invention.

In accordance with the embodiment shown in Figure 6, mobile guide 230 is configured as an elongated tube having a length that is greater than the length of haptic 251. The length of guide 230 may alternatively be equivalent to or less than the length of haptic 251. However, the excess length of guide 230 is

believed desirable as it may simplify use of guide 230 with certain insertor devices. For example, the length of mobile guide 230 is preferably greater than the length of a sleeve, such as sleeve 220 shown in Figure 2, to permit easy manipulation of guide 230 when used in combination with sleeve 220, as will be described in greater detail with reference to Figures 6-9. The outer periphery of guide 230 is sufficiently large to accommodate haptic 251, yet small enough to permit guide 230 to pass substantially freely through sleeve 220.

The length of guide 230, in accordance with the embodiment shown in Figures 7-9, is designed to exceed the length of haptic 251 and sleeve 220. Guide 230, depending on a number of factors including the size, shape, and length of a haptic 251, intraocular lens 250, and sleeve 220, may have a length ranging from approximately 2 mm to approximately 50 mm or more, and preferably, from approximately 3mm to approximately 33 mm. The lower values within these ranges are intended to represent a length comparable to the length of a haptic. Initially, as is shown in Figure 7, guide 230 is inserted into sleeve 220 such that a portion of guide 230 protrudes from the proximal opening 224 of sleeve 220. With the proximal end 234 of guide 230 protruding slightly from the proximal opening 224 of sleeve 220, the surgeon may apply a buffer to guide 230 and sleeve 220 at the same time the lens 250 is inserted into sleeve 220.

The guide 230 includes a kink 232 or other stop mechanism, such as an outwardly extending tab or bump for example, which provides a minimal holding force to prevent guide 230 from unintentionally slipping out of sleeve 220. Alternatively, the stop mechanism may be provided on a wall of sleeve 220 adjacent guide 230 or on respective walls of guide 230 and sleeve 220. Other stop mechanisms that perform the function of preventing unintended slippage between the guide 230 and sleeve 220 may be employed. A surgeon may move guide 230 captured in sleeve 220 toward either of the proximal or distal openings 224, 226 of sleeve 220 by applying a force sufficient to overcome the frictional or mechanical forces generated between kink 232 and the adjacent wall of sleeve

220. In this manner, guide 230 in combination with sleeve 220 provides a stable and easily manipulated structure which reduces the difficulty of loading the intraocular lens 250 into sleeve 220.

After guide 230 is inserted into sleeve 220, as is shown in Figure 7, distal haptic 251 may easily be advanced into the proximal opening 234 of guide 230, typically by the surgeon grasping intraocular lens 250 with forceps 256 or other device designed to manipulate intraocular lens 250. The proximal end 234 of guide 230 is configured to accommodate the shape of the intraocular lens body at the contact point between distal haptic 251 and the lens body. Intraocular lens 250 and guide 230 may then be advanced into the proximal opening 224 of sleeve 220.

As can be seen in Figure 8, distal haptic 251 is safely protected by guide 230 from potential damage due to bending or misalignment as intraocular lens 250 is advanced into sleeve 220. For example, and with reference to Figure 2, direct contact between distal haptic 251 and a constriction 227 of sleeve 220 that may otherwise lead to detrimental bending or misalignment of distal haptic 251 (e.g., bent distal haptic 251') while loading intraocular lens 251 into an insertor device is altogether precluded.

Intraocular lens 250 and guide 230 are advanced into sleeve 220 until intraocular lens 250 is properly situated within sleeve 220, as is shown in Figure 9. Guide 230, having performed its protective function during loading of intraocular lens 250, may then be removed through the distal opening 226 of sleeve 220 by the surgeon and discarded prior to inserting intraocular lens 250 into the eye.

In the embodiment illustrated in Figures 6-9, guide 230 is depicted as having an elongated tubular configuration. It is to be understood that guide 230 may have a configuration other than an elongated tubular configuration. In an alternative embodiment, guide 230 may have a configuration that includes an elongated channel. Other guide structures and configurations that protect distal

haptic 251 and/or proximal haptic 253 from damage during loading of an intraocular lens into an insertor device come within the scope of the present invention.

Guide 230, as shown in Figure 6, has a relatively thin wall and a stiffness sufficient to partially straighten distal haptic 251 from its original curved configuration. The wall of guide 230 typically has a thickness ranging from approximately 0.01 mm to approximately 0.25 mm, and preferably from approximately 0.025 mm to approximately 0.10 mm. The outer diameter of guide 230 typically ranges from approximately 0.30 mm to approximately 3.0 mm. The ratio of guide wall thickness with respect to outer diameter of guide 230 typically ranges from approximately 1:5 to approximately 1:25. In an embodiment that includes guide 230 in combination with a sleeve as described herein, the ratio of the outer diameter of sleeve 220 with respect to the outer diameter of guide 230 typically ranges between approximately 1.25 to approximately 10, and preferably between approximately 2 to approximately 5 or more preferably, between approximately 3 to approximately 4.

In an embodiment in which guide 230 is used in combination with sleeve 220 shown in Figures 7-9, the length of sleeve 220 is typically at least approximately 10 mm and typically less than approximately 50 mm. The thickness of the sleeve wall toward the proximal opening 224 is approximately 0.01 mm to approximately 0.1 mm. The thickness of the wall of the distal opening 226 is approximately 1.5 mm to approximately 3.5 mm. The tubular portion of the wall is typically constant from the distal opening 226 to approximately the tapered portion 227 of sleeve 220. Distal opening 226 is preferably beveled, from about 16 ° to about 75° much like the tip of a needle to ease insertion of the implant into the eye, although a variety of configurations to distal opening 226 are possible. Distal opening 226 of sleeve 220 may take on a variety of other shapes and, in one embodiment, distal opening 226 is ellipsoid or

circular in cross-section. Alternatively, distal opening 226 of sleeve 220 may be tapered or flared.

The proximal opening 224 of sleeve 220 may have a width ranging from at least approximately 1.5 mm to less than approximately 10 mm, and preferably greater than approximately 3 mm and less than approximately 9 mm. The walls of the material used to prepare sleeve 220 may have a variety of thicknesses provided that sleeve 220 remains readily compressible by, for example, forcep blades 256, and maintains its integrity during use and is sufficiently deformable to permit positioning of intraocular lens 250 within sleeve 220. As was previously discussed, the proximal opening 224 of sleeve 220 may have any of a variety of configurations including, but not limited to, straight edges, chamfered edges, or curved edges either concave or convex curves relative to the tip of sleeve 220. Alternatively, the proximal opening 224 of sleeve 220 may be angled.

Sleeve 220 also includes a distal opening 226 in the tubular portion of sleeve 220 and the width of sleeve 220 preferably decreases over at least a portion of the sleeve from proximal opening 224 to distal opening 226 to provide a tapered portion 227 to sleeve 220. In one embodiment, the tapered portion 227of sleeve 220 reduces the dimension of the sleeve from the proximal opening 224 to the distal opening 226 within one-half of the length of the sleeve. The tapered portion 227 reduces the width of sleeve 220 toward the distal portion of the sleeve. Distal opening 226 is typically at least about 1 mm in diameter and preferably less than about 4 mm in diameter with preferred dimensions for an intraocular lens insertor of between about 2 mm to about 3 mm for soft flexible lenses and as much as 4 mm for less flexible lenses such as acrylic lenses.

Sleeve 220 and guide 230 may be fabricated from similar materials, such as from a compressible, flexible, deformable, and smooth material. One suitable material is a flexible polymeric material including a Teflon material, such as ethylene tetrafluoroethylene (ETFE, Zeus Corp. Orangeburg. S.C.), but other

materials can be used, including, but not limited to: other tetrafluoroethylenes (e.g., polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), perfluoro-alkoxy fluorocarbons (PFA), chlorotrifluoroethylene (CTFE), flexible vinyls (e.g., polyvinyl chloride or polyvinylide fluoride (PVDF))), polyimide, polyamide, polyester, silicones, polyolefin materials, polyetherketone (PEEK), non-opaque TEFLON, polyvinyl chloride with a hardness range of about 35D to about 80D, etc. In general, any plastic material capable of being extruded, shaped and formed or molded may be used.

Preferred materials for use in fabricating sleeve 220 and guide 230 are sufficiently non-opaque so that an implant can be seen in the sleeve when positioned therein. Sleeve 220 and guide 230 may be formed from a flexible, deformable, and compressible tubing (e.g., ETFE, PTFE or PFA tubing) that is preferably malleable and capable of being pressed or distended. Alternatively, sleeve 220 and guide 230 may be injection molded.

Sleeve 220 shown in Figures 7-9, for example, is illustrated as a single piece sleeve, that is, a completely integral structure. However, it is also contemplated that guide 230 may be used with sleeves constructed from two or more pieces that form a multi-piece sleeve. Figures 5a and 5b illustrate an embodiment of a multi-piece sleeve which may be used in combination with a mobile guide of the present invention. The sleeve 221 comprises a first opening 225 at the proximal portion of the sleeve, a second opening 228, with a beveled tip, at the distal portion of the sleeve and a tapered portion 229 with the connection 231 between the two pieces preferably positioned just distal to the tapered portion 229. The sleeve pieces can be used as an intact sleeve or the portion of the sleeve including the first opening 225 may be discarded while that portion of the sleeve including the second opening 228 and the lens 250 may be used separately. Alternatively, a lens in a uniformly tubular sleeve can also be employed, such as that portion of the sleeve with opening 228 illustrated in Figure 5b.

In one embodiment, both proximal and distal portions of the sleeve are prepared from ETFE, PTFE, or the like, and in another embodiment, that part of the sleeve including second opening 228 is prepared from ETFE or PTFE while that portion of the sleeve including first opening 225 may comprise an elastic portion such as a soft silicone, an elastomeric latex, or another flexible material. Alternatively, the multi-piece sleeve 221 may be prepared from materials with different hardnesses. In one embodiment, that portion of the sleeve including first opening 225 may be prepared from a flexible, deformable material while that part of the sleeve including second opening 228 may be more rigid. Where the sleeve 221 is provided as a multi-piece sleeve, preferably the portions of the sleeve 221 are affixed to each other by any suitable method or material including, but not limited to, an epoxy bond, a heat bond, silicone adhesive, acrylic adhesive, welding (e.g., ultrasonic, laser, etc.).

Further, sleeve 220 and guide 230 may be coated on their respective interior or exterior surfaces with a variety of friction reducing materials to ease the passage of a haptic into guide 230 and a lens 250/guide 230 assembly through the length of sleeve 220. The coatings may, for example, reduce friction on lens 250 by sleeve 220. Preferred coating materials include, but are not limited to, silicones, such as HYDRO-SIL (TUA Systems, Sarasota, FL), ion - exchange hydrophilic treatments, such as HYDRO-SILK or other coatings including, but not limited to, heparin, PARYLENE (Nova Tran Corp., Clear Lake, WI), or NOVA TRAN (Nova Tran Corp), etc.

As was discussed previously, the insertor devices shown in Figures 1, 10, and 11or that shown in Figure 3, represent two of a wide variety of insertor devices that may be employed in combination with a mobile guide of the present invention to prevent damage to a haptic or other securing member of an intraocular lens while the lens is loaded into the insertor device. It is to be understood that the mobile guide of the present invention may be employed in any device for inserting an intraocular lens into the eye, and that the insertor

devices characterized herein are intended to provide an illustrative environment of use within which the features and advantages of the mobile guide of the present invention may be described and appreciated. For example, a number of exemplary insertor devices that may be used in combination with a mobile guide of the present invention are disclosed in the aforementioned U.S. patents.

Additional features of an exemplary intraocular lens insertor device that employs a mobile guide of the present invention will now be described in greater detail with reference to Figures 1, 10, and 11. Referring again to Figure 1, the insertor device 10 includes a collet 18 to engage sleeve 20 and maintain orientation of sleeve 20 in the device. Collet 18 is substantially hollow to form an internal lumen 47 (Figure 1b) and comprises a proximal end 42 and a distal portion 46. Collet 18 is preferably slightly tapered down its length and in a preferred embodiment, collet 18 includes at least two slits 43 (see Figure 1a) for immobilizing the sleeve 20 in the device and a notched portion 49, or other means, for engaging hand-piece 12 and preventing rotation of hand-piece12 relative to collet 18 during use. Those of ordinary skill in the art will recognize that there are a variety of modifications to the collet, hand-piece or ring-clamp that could be used to immobilize the sleeve of this invention and that, for purposes of this invention, an immobilized sleeve is an important and preferred aspect of this invention.

In a preferred embodiment, the internal lumen 47 of the collet 18 tapers toward the distal portion 46 of collet 18 to guide blades 16 toward the implant and to permit the blades to track smoothly as they advance the implant toward second opening 26 of sleeve 20. The distal portion 46 of collet 18 may take on any of a variety of cross-sectional configurations, including: a round configuration; a rhomboid configuration; a winged circular configuration; an expanded winged circular configuration; an even more expanded winged circular configuration; and a scrolled configuration, for example. Two edges of the

rhombus, in a rhomboid configuration, and the winged portions by cross-section, in a winged configuration, are available as guides for blades 16.

In addition to the modifications to the distal portion of the internal surface of collet 18, the internal surfaces of the lumen formed in collet 18 can be modified in other ways. For example, lumen 47 can be modified as illustrated in cross-section G-G through collet 18 (see Figure 1b). This shape provides guidance and lateral stability to blades 16. Alternatively, modifications to the internal surfaces of the collet or where a collet is not used, the internal surface of the hand-piece can include guides such as those provided in Figure 11 or follow those of Rheinish et al. (U.S. Pat. No. 5,275,604). Further, the cross-sectional dimension of the internal lumen of the collet also preferably narrows from the proximal portion toward the distal portion of the collet 18 to permit blades 16 to track smoothly into contact with sleeve 20 when sleeve 20 is loaded into device 10. Importantly, the guides are positioned outside of the flexible sleeve and therefore do not contact the implant directly.

Hand-piece 12 (Figure 1) includes an elongate shaft preferably with a flange 45 at its proximal portion and threads 47 at its distal portion. Hand-piece 12 is preferably substantially hollow and is adapted to receive pusher 14. Distal portion 48 (see Figure 7) of hand-piece 12 is preferably adapted to receive notched portion 49 of collet 18. Distal portion 48 is also preferably threaded to receive ring clamp 22. Optionally hand-piece 12 also includes grips such as longitudinal grooves or roughened portions along its length to prevent sliding and unwanted rotational movement during use.

Pusher element 14 is preferably an extended rod that is adapted to fit within the hollow portion of hand-piece 12 and to mate in contour with hand-piece 12. Pusher element 14 preferably includes a broadened proximal portion 51 to facilitate movement of the pusher element 14 relative to hand-piece 12. Optionally, guides or ridges on the outer surface of pusher element 14 can be

added to mate with matching receiving guides within the hollowed portion of hand-piece 12.

In one embodiment, the insertor device 10 is equipped with at least two blades 16 (see Figures 1, 10, and 11) affixed to the distal portion of pusher element 14. The blades 16 provide a means for compressing a sleeve and a means for advancing the compressed area of the sleeve toward the distal end of the sleeve in order to gently urge lens 50 out of sleeve 20. In another embodiment, the insertor device 10 is equipped with a pushrod (see Figure 3) affixed to the distal portion of pusher element 14 which is used to gently advance the lens 50 out of sleeve 20. This embodiment will be later described in detail with reference to Figures 3a-3b.

In an embodiment of an insertor device 10 which employs a least two blades 16, such as that shown in Figures 1, 10, and 11, the blades 16 may be prepared from a variety of materials including, but not limited to, TEFLON, plastic, metal-reinforced plastic, stainless steel or other rigid materials. In a preferred embodiment, blades 16 are prepared from stainless steel wire, such as hard spring temper type 302 stainless steel wire rolled flat having a tensile strength of about 280,000 psi or type 17-7 precipitation hardening (PH) stainless steel drawn wire rolled flat and then heat treated to 240,000 psi in a vacuum or as much as 320,000 psi (Supreme Steel Treating Inc., El Monte, CA). However, steel wire greater than about 60,000 psi is also considered suitable for the blades of this invention. Those of ordinary skill in the art will recognize that the rigidity of the blade is a function of the type of material, the length of the blade and the thickness of the blade and that the selection of the material will also take into account the type of implant to be inserted into a portion of the body. Some plastics can be used, but plastic blades may be thicker than steel blades to provide sufficient rigidity to the blades.

In one embodiment, using two blades for lens insertion, the blades 16 are at least 1 centimeter (cm) in length and preferably less than about 10 cm in

length. For an intraocular lens embodiment, the blades are preferably greater than about 3.5 cm and preferably less than about 6 cm in length and more preferably less than about 4.5 cm in length. Also, each blade is preferably at least about 1 mm in width and preferably less than about 10 mm in width. The length that the sleeve is selected to extend beyond collet 18 can vary and the length of blades 16 will vary with this length. Also, each blade is at least about 0.25 mm in thickness and preferably less than about 1.5 mm in thickness. However, blades of as thin as 0.1 mm could function in a small, compact insertor.

In another embodiment, the blades 16 are formed such that the tips of the blades bend slightly together. Those skilled in the art will recognize that the extent of the bend in the blades can be varied somewhat, particularly depending on the overall dimensions of the device. For example, the blades can be bent or curved in a slight arch or curved or bent slightly inward toward each other at one or more locations along the length of the blades. For example, blades can be curved inwardly from about 1 mm to about 10 mm relative to the plane formed by the blade. Alternatively, the tip of the blade can be bent slightly such as from about 0.02 mm to about 0.2 mm relative to the plane formed by the blade. Blades 16 can be polished, as needed, to further reduce friction of the blades either in the hand-piece 12, the collet 18, or on sleeve 20. The blades can be affixed to the pusher element using adhesives, crimping, pinning or a variety of means known to those of ordinary skill in the art.

The squeezing action of a blade or blades on a flexible and compressible sleeve containing one or more implants produces a controlled and deliberate movement of the implant through the sleeve along a predetermined axis of motion, defined by the sleeve, and at a controlled rate. Those of ordinary skill in the art will recognize that other mechanisms employing these means can be incorporated into the devices of this invention. Those of ordinary skill in the art will further recognize that forces on the flexible and compressible sleeve from

the blade(s) and the frictional forces between the sleeve and the implant can be increased or decreased to maximize controlled movement of the lens implant through the device and into the eye.

Device 10 also includes a ring clamp 22 adapted to fit over collet 18 and to secure onto hand-piece 12. Ring clamp 22 further compresses the sides of collet 18 to squeeze clamp the sleeve 20 within the collet 18 during use. Those of ordinary skill in the art will recognize that the ring clamp is not necessary and that device can be configured to secure the collet or its equivalent to the pusher element and to immobilize the sleeve in a variety of ways. Alternatively, the collet can be included as part of the hand-piece.

To assemble device 10, a sleeve 20, preferably containing a lens 50 (see Figure 1) between second opening 26 and tapered portion 28 (i.e., preferably substantially within the tubular portion of the sleeve) is introduced into lumen 47 of collet 18. Referring again to Figure 1, there is illustrated a view of the proximal portion of collet 18 by cross-section. That portion of the sleeve 20 with second opening 26 is introduced into the length of collet 18 such that first opening 24 of sleeve 20 is positioned within the proximal portion of collet 18 and is positioned between slits 44 but preferably does not extend beyond slits 44 past the dimension of collet 18. Second opening 26 of sleeve 20 preferably extends beyond the distal portion of collet 18. Pusher element 14 with blades 16 is then introduced into hand-piece 12. Next, blades 16 are positioned on either side of sleeve 20 and moved toward the distal portion of the collet 18 preferably until resistance is felt on the blades due to the contact between blades 16 and that portion of sleeve 20 containing lens 50. Collet 18 is next positioned onto the distal portion of hand-piece 12, preferably mating by notch 49 on collet 18 with a groove on hand-piece 12. Ring clamp 22 is positioned over sleeve 20 and around collet 18 and is securely engaged onto the distal portion of hand-piece 12. In use, pusher element 14 is pushed forward to move blades 16 down the length of sleeve 20 to gently urge lens 50 out of sleeve 20.

Figure 10 provides a view of the assembled device 10 in cross-section and Figure 11 provides a second cross-sectional view of the assembled device rotated 90° relative to Figure 10. Here, sleeve 20 contains a lens 50. The proximal portion containing first opening 24 of sleeve 20 is engaged within the proximal portion of collet 18, and collet 18 is positioned onto the distal end of hand-piece 12. Pusher element 14 is positioned within hand-piece 12, blades 16 are positioned on either side of sleeve 20, and ring clamp 22 is in place to secure sleeve 20 within collet 18 and to further secure collet 18 onto hand-piece 12. Movement of pusher element 14 relative to hand-piece 12 moves blades 16 toward the distal portion of the device and gently squeezes or urges lens 50 forward and out of sleeve 20.

The hand-piece, pusher element, collet and ring clamp can be prepared from a variety of durable, stiff materials such as hard plastics, including moldable plastics, acrylics, styrene, clear, opaque or non-opaque materials. Those with ordinary skill in the art will appreciate the advantages of a non-opaque collet, for example, that permits the continued viewing of the lens during insertion. Hand-piece 12 and other hand-pieces of this invention can further be prepared from stainless steel, polysulfone, polycarbonates, nylons, acetals or other suitable materials with or without glass, carbon or graphite fillers. The pieces can be prepared from heat or irradiation-stable materials for reuse or prepared as a disposable for single-use applications.

Figure 3 illustrates an additional insertor embodiment that may be used in combination with a mobile guide of the present invention. The embodiment of an insertor device shown in Figure 3 employs a flexible, deformable sleeve together with a pushrod to mobilize an implant from an insertor into the eye. In Figure 3a, an insertor 700 includes a flexible sleeve 702, a collet 704, and a ring clamp 706. A hand-piece 708 includes a pusher-element 710 or other means for mobilizing a pushrod 712. The pushrod 712 is preferably rounded at the tip 714 to minimize trauma to the implant when the implant is mobilized in the sleeve

702 but the pushrod could also be flattened or grooved. The pushrod 712 is preferably prepared from either the same or similar material as the hand piece or alternatively prepared from stainless steel, TEFLON, acrylic, vinyl, polysulfone, or the like.

To assemble, the sleeve 702, collet 704 and ring clamp 706 are assembled such that the pushrod 712 extends from the hand-piece sufficiently so that it can be positioned within the first opening of the sleeve 702 as the ring clamp 706 is position and affixed to the hand-piece 708. At least one indexing extension 713 preferably extends from the distal portion of the hand-piece to key or mate with the proximal portion of the collet 704. The extensions prevent rotation of the collet 704 relative to the hand-piece 708 as the ring clamp 706 is secured to the hand-piece 708. The ring clamp 706 secures the collet 704 to the device and provides a clamping force to immobilize sleeve 702 between slits 716 of collet 704.

An illustration of the device shown in Figure 3a as assembled is provided in Figure 3b. A cross-section of the device through E-E of Figure 3b is illustrated in Figure 3c. Here, ring clamp 706 surrounds the proximal portion of collet 704. Sleeve 702 is positioned within the lumen 718 of collet 704 with pushrod 712 positioned within sleeve 702. Ring clamp 706 provides a clamping force to immobilize sleeve 702 within the device 700. The ring clamp 706, a screw, and other pressure fit elements are contemplated to immobilize the sleeve in the insertor.

Once assembled, an incision into the eye is prepared and the sleeve 702 is positioned in or adjacent to the incision. The pushrod 710 is gently activated to advance the pushrod toward the distal portion of the device, thereby mobilizing the implant in the sleeve 702 and from the sleeve into the body. While either the blade embodiment or the pushrod embodiment will function with the flexible, deformable sleeves of this invention, the blades may be better suited for more fragile implants. Advantageously, the pushrod device in combination with the

sleeve of this invention requires little force to mobilize an implant so that the likelihood of damaging the implant with the pushrod is low.

In accordance with another embodiment of the present invention, the physician may purchase a mobile guide and a sleeve supplied without a lens implant. The physician may also purchase a sleeve supporting device. The mobile guide may be inserted into a first proximal opening of the sleeve. The physician may then introduce a suitable lubricant, by syringe or pipette, into one or both ends of sleeve and guide before introducing the securing member, such as a haptic, into the mobile guide. Next, the lens implant, such as an intraocular lens, is positioned proximate the proximal opening of the guide.

If a pair of forceps is used, care is taken to gently position the leading haptic of the lens into the guide. The lens/guide assembly is then advanced just inside the proximal opening of the sleeve or, alternatively, positioned directly into the tapered sleeve portion and into at least part of the tubular portion of the sleeve. The sleeve supporting device may be used to stabilize the sleeve when loading the intraocular lens/guide assembly into the sleeve. Optionally, the lens implant may be deformed, such as by using a forceps, prior or concurrently with the introduction of the lens implant into the sleeve.

For example, the lens implant may be folded slightly (i.e., less than 20% of the diameter of the lens) or substantially (i.e., greater than 50% of the diameter of the lens) before the lens/guide assembly is introduced into the sleeve. Preferably, where the implant is a multi-piece intraocular lens with filament haptics, the lens is introduced into the sleeve with one haptic, protected by the mobile guide, positioned in front of the lens and the second haptic trailing the lens. The second haptic may also be protected by a mobile guide, such that plural guides are employed for a single lens/guide assembly.

Those skilled in the art will recognize that lenses having securing members protected with mobile guides may be placed into a sleeve or similar structure of an insertor device in a variety of orientations without altering the

scope of the present invention. A mobile guide in accordance with the present invention is intended to accommodate a variety of lens implants provided with haptic-like securing members, including, but not limited to, single piece intraocular lenses and three or more piece composite intraocular lenses that employ a plurality of haptic supports.

Figure 4 illustrates an embodiment of a sleeve supporting device in accordance with the principles of the present invention. The sleeve holder 650 is preferably prepared from a substantially rigid material such as a plastic, including thermoplastic polymers, as well as acrylics, hard silicones, nylon, rubber, and the like. In a preferred embodiment, the sleeve holder 650 is prepared from a sufficiently clear material to permit visualization of the implant in the sleeve when the sleeve is in position in the holder. The sleeve holder 650 includes a hollowed portion that is slightly larger but generally conforms in shape to the shape of sleeve 652 or another type of sleeve. The sleeve 652 of Figure 4 includes a first opening 654 and a second opening 656. The first opening 654 is preferably larger than second opening 656 and preferably the periphery of first opening 654 is from about 4.5 mm to about 10 mm and the periphery of the second opening 656 is from about 1.5 mm to about 4 mm. A preferred length of the holder 650 is from about 2 cm to about 4 cm.

The sleeve holder 650 adds support to the flexible deformable sleeve during insertion of an implant, such as an intraocular lens 658 into the sleeve. The sleeve holder can take any of a variety of shapes and preferably the shape and size of the holder permit it to be held in one hand while inserting a mobile guide 661 and lens implant 658 into a sleeve 652 in the holder 650 with the other hand. In Figure 4, the holder is rectangular in shape, but those of ordinary skill in the art will recognize that a variety of holder shapes and sizes can be prepared to accommodate sleeves in view of this disclosure. The combination of a sleeve and mobile guide of this invention together with a sleeve holder forms an

implant loading system in accordance with the principles of the present invention.

In use, the sleeve 652 is positioned in the support block 650 before or after lubricating the sleeve with a suitable friction-reducing agent or buffer. The mobile guide 661 is partially installed into sleeve 652 with a portion of the proximal end of guide 661 protruding from the first opening 654 of sleeve 652. The leading haptic 653 of intraocular lens 658 is inserted into the proximal opening of guide 661. The lens/guide assembly is then inserted into the first opening 654 using a forceps 660, fingers, or the like. The lens 658 and guide 653 are urged into the first opening 654 and are positioned preferably past the tapered portion 662 of sleeve 652 and at least partially into the tubular portion 655 of the sleeve. After appropriately positioning lens 658 within sleeve 652, mobile guide 661 is removed from haptic 653.

The sleeve 652 is preferably able to distend or stretch to accommodate the additional bulk of the forceps 660 when forceps 660 is introduced into the sleeve 652 with the lens implant 658. Optionally, the lens implant 658 may be deformed slightly to encourage folding in a desired direction when the lens 658 is introduced into the sleeve 652, using, for example, lateral pressure while introducing the lens 658 into the tapered portion 662 and into at least a part of the tubular portion. The forceps 660 is removed from the first opening 654 and the sleeve 652 is removed from holder 650. The sleeve holder is preferably reusable and can optionally be disposable or sterilizable such as by autoclaving, ethylene oxide, or ultraviolet light.

The present invention also relates to a kit comprising a guide of this invention, a sleeve or other lens containment/manipulating structure, and a lens implant, such as an intraocular lens. Optionally, the kit may include an insertor device, such as that shown in Figures 1, 3, 10, and 11, and/or a sleeve stabilizing device, such as that shown in Figure 4. Further, the elements of the kit may be

arranged in a variety of combinations and packed in a tray or package suitable for shipping.

The foregoing description of the various embodiments of the invention has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Many modifications and variations are possible in light of the above teaching. It is intended that the scope of the invention be limited not by this detailed description, but rather by the claims appended hereto.

What is Claimed is:

1. An apparatus for protecting an implantable lens, comprising:

an intraocular lens having a support; and

a guide separate from, and movable with, the support, the guide protecting the support from damage during loading of the intraocular lens into an insertor device;

whereby the guide is removed from the support prior to inserting the intraocular lens into an eye using the insertor device.

2. The apparatus of claim 1, further comprising a sleeve configured to receive the guide and the intraocular lens.

3. The apparatus of claim 2, wherein the guide has a length greater than a length of the sleeve.

4. The apparatus of claim 1, wherein the guide has a length ranging from approximately 2 mm to approximately 50 mm.

5. The apparatus of claim 2, further comprising a stop mechanism to prevent unintended slippage of the guide relative to the sleeve.

6. The apparatus of claim 5, wherein the stop mechanism comprises a deformation on a surface of the guide.

7. The apparatus of claim 1, wherein the guide comprises an elongated tubular structure or an elongated channeled structure.

8. The apparatus of claim 1, wherein the guide is fabricated from a flexible tubular material.

9. The apparatus of claim 1, wherein the guide comprises polymeric tubing.

10. The apparatus of claim 1, wherein the guide is fabricated from a non-opaque material.

11. The apparatus of claim 1, wherein the guide comprises tubing fabricated from a Teflon material.

12. The apparatus of claim 1, wherein the guide comprises tubing fabricated from PTFE or ETFE.

13. The apparatus of claim 1, wherein the guide comprises an elongated tubular structure including a wall having a thickness ranging from approximately 0.01 mm to approximately 0.25 mm.

14. The apparatus of claim 1, wherein the guide comprises an elongated tubular structure having an outer diameter ranging from approximately 0.30 mm to approximately 3.0 mm.

15. The apparatus of claim 1, wherein the guide comprises an elongated tubular structure including an outer diameter and a wall having a thickness, a ratio of the wall thickness with respect to the outer diameter ranging from approximately 1:5 to approximately 1:25.

16. The apparatus of claim 1, further comprising a sleeve configured to receive the guide and the intraocular lens, a ratio of an outer periphery of the

sleeve with respect to an outer periphery of the guide ranging between approximately 1.25 to approximately 10.

17. An apparatus for protecting an implantable lens from damage, comprising:

an intraocular lens having a support;

a guide separate from, and movable with, the support; and

a sleeve configured to receive the guide and the intraocular lens;

whereby the guide protects the support from damage during loading of the intraocular lens into the sleeve and is removed from the support prior to inserting the intraocular lens into an eye.

18. The apparatus of claim 17, wherein the guide has a length greater than a length of the sleeve.

19. The apparatus of claim 17, further comprising a stop mechanism to prevent unintended slippage between the guide and the sleeve.

20. The apparatus of claim 19, wherein the stop mechanism comprises a deformation on a surface of either one or both of the guide and sleeve.

21. The apparatus of claim 17, wherein the guide comprises an elongated tubular or channeled structure fabricated from a flexible material.

22. The apparatus of claim 17, wherein the guide comprises non-opaque, polymeric tubing.

23. The apparatus of claim 17, wherein the guide comprises tubing fabricated from a Teflon material.

24. The apparatus of claim 17, wherein the guide comprises an elongated tubular structure including a wall having a thickness ranging from approximately 0.01 mm to approximately 0.25 mm and an outer diameter ranging from approximately 0.30 mm to approximately 3.0 mm.

25. The apparatus of claim 17, wherein the guide comprises an elongated tubular structure including an outer diameter and a wall having a thickness, a ratio of the wall thickness with respect to the outer diameter ranging from approximately 1:5 to approximately 1:25.

26. The apparatus of claim 17, wherein a ratio of an outer diameter of the sleeve with respect to an outer diameter of the guide ranges between approximately 1.25 to approximately 10.

27. A system for loading an intraocular lens into an insertor device, comprising:

a resilient sleeve having a first opening, a second opening, and a longitudinal axis;

a guide engaging a support of the intraocular lens, the guide exerting a force on the support to urge a leading end of the support toward the longitudinal axis of the sleeve; and

a lens manipulating device that advances the intraocular lens and guide into the first opening of the sleeve, whereby the leading end of the support is protected from damage by the guide, and the guide is separated from the support and removed through the second opening prior to inserting the intraocular lens into an eye using the insertor device.

28. The system of claim 27, wherein the guide comprises an elongated tube having a proximal opening for receiving the leading end of the support.

29. The system of claim 27, wherein a width of the first opening ranges from approximately 4.5 mm to approximately 10 mm, and a width of the second opening ranges from approximately 1.5 mm to approximately 4 mm.

30. The system of claim 27, wherein the guide has a length greater than a length of the sleeve.

31. The system of claim 27, further comprising a stop mechanism to prevent unintended slippage between the guide and the sleeve.

32. The system of claim 27, wherein the guide comprises non-opaque, polymeric tubing.

33. The apparatus of claim 27, wherein the guide comprises an elongated tubular structure including a wall having a thickness ranging from approximately 0.01 mm to approximately 0.25 mm and an outer diameter ranging from approximately 0.30 mm to approximately 3.0 mm.

34. The apparatus of claim 27, wherein the guide comprises an elongated tubular structure including an outer diameter and a wall having a thickness, a ratio of the wall thickness with respect to the outer diameter ranging from approximately 1:5 to approximately 1:25.

35. The apparatus of claim 27, wherein a ratio of an outer periphery of the sleeve with respect to an outer periphery of the guide ranges between approximately 1.25 to approximately 10.

36. A kit comprising:

an intraocular lens;

a resilient sleeve comprising a first opening and a second opening, the sleeve configured for receiving the intraocular lens; and

a guide comprising an elongated member, the member having an inner periphery dimensioned to receive a support of the intraocular lens and an outer periphery smaller than a width of the first and second openings of the sleeve, the guide adapted for movably guiding the lens so as to prevent damage to the lens as the lens is loaded into the sleeve.

37. The kit of claim 36, further comprising a lens manipulating device.

38. The kit of claim 36, further comprising a hand-held insertor device.

39. The kit of claim 36, further comprising a sleeve supporting device configured to stabilize the sleeve.

40. The kit of claim 36, wherein either one or both of the sleeve and the guide are fabricated from non-opaque material.

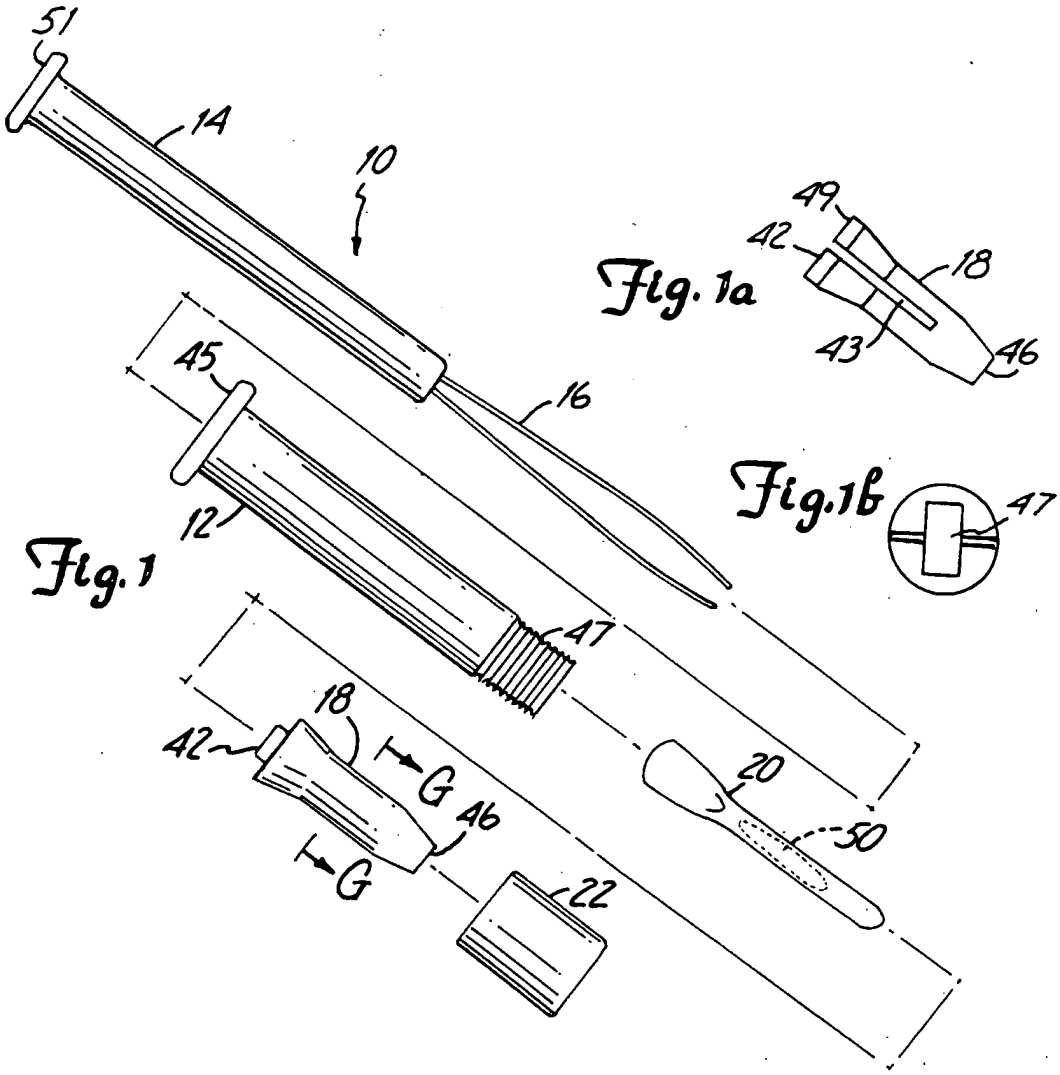
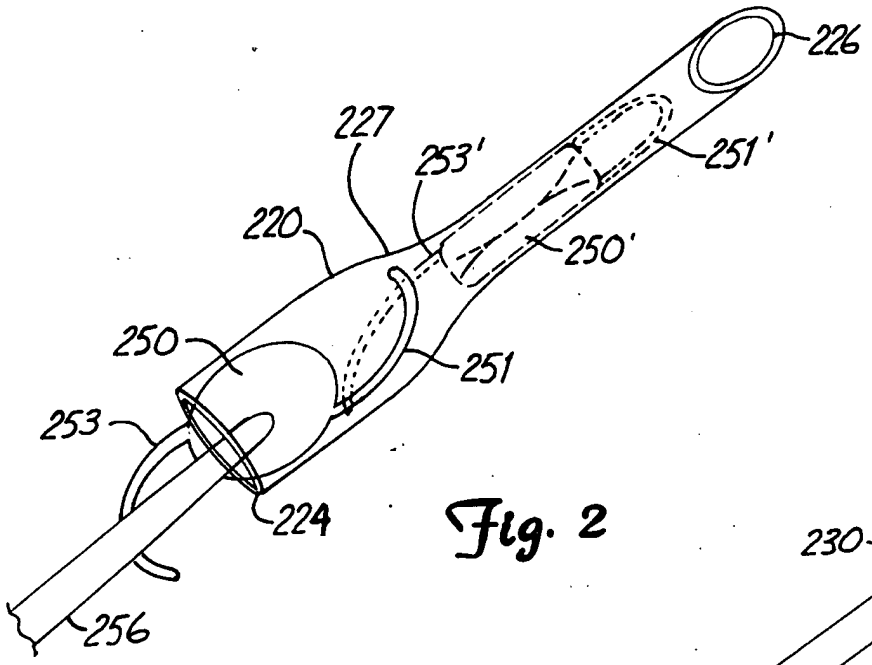


Fig. 1

Fig. 1a

Fig. 1b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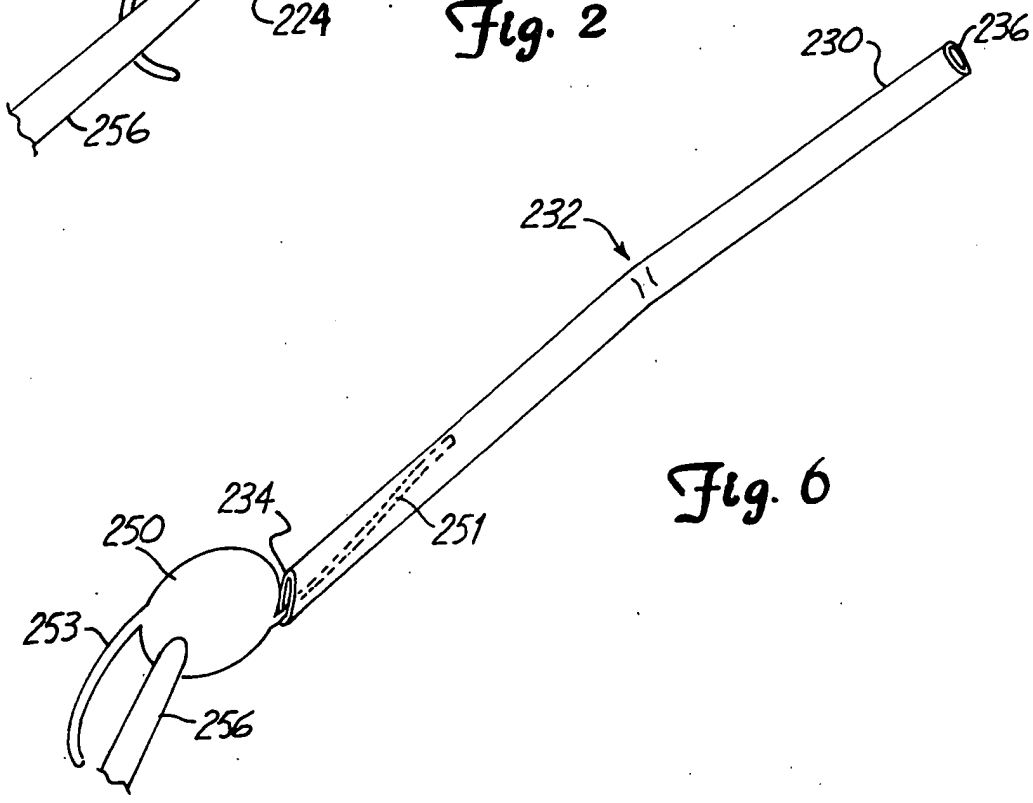
253
224
256

Fig. 2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256

Fig. 6

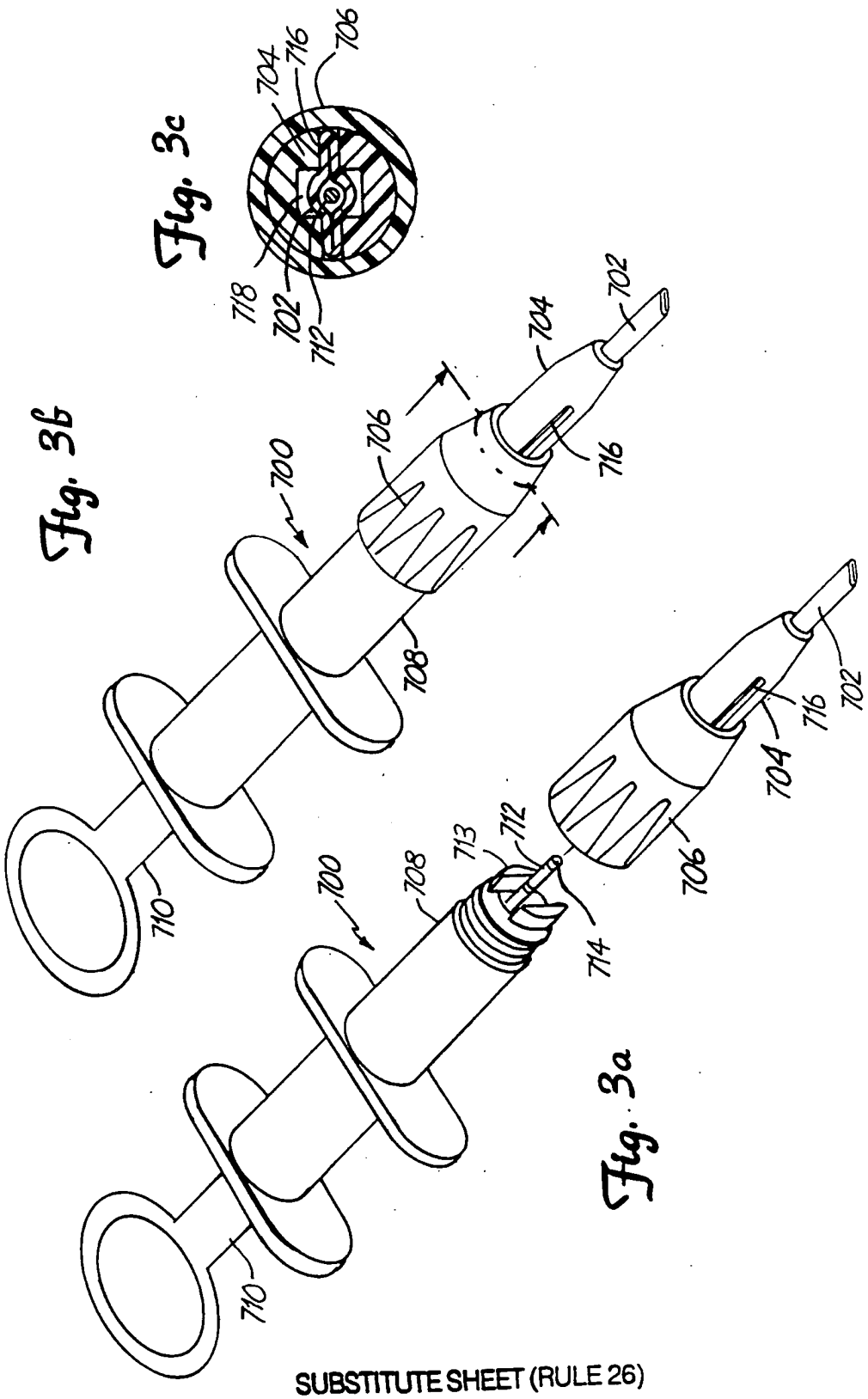


Fig. 3c

Fig. 3b

Fig. 3a

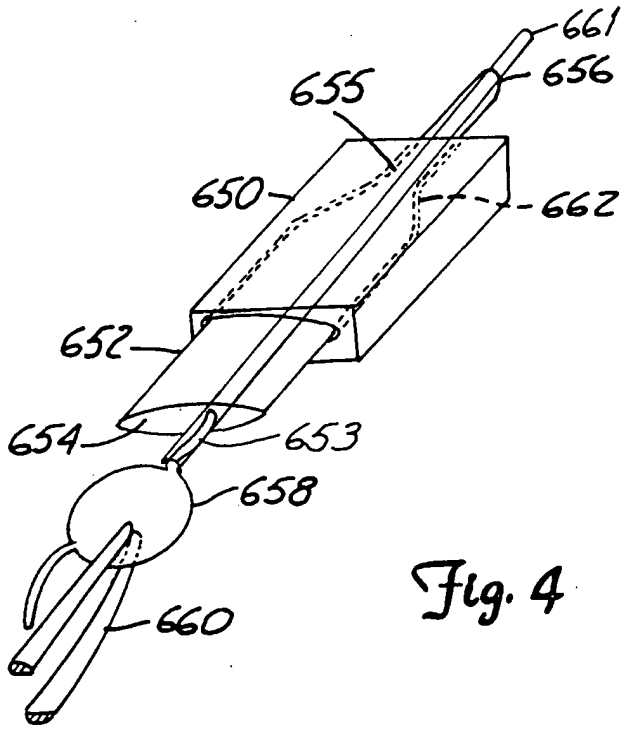


Fig. 4

Fig. 5a

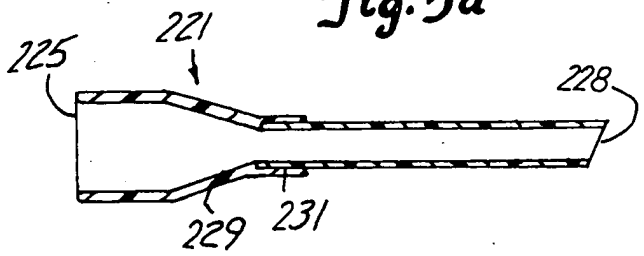
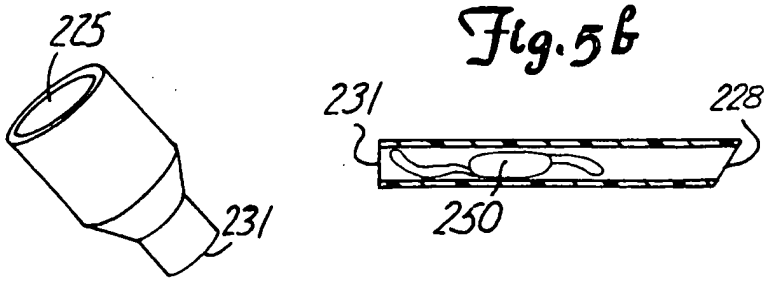


Fig. 5b



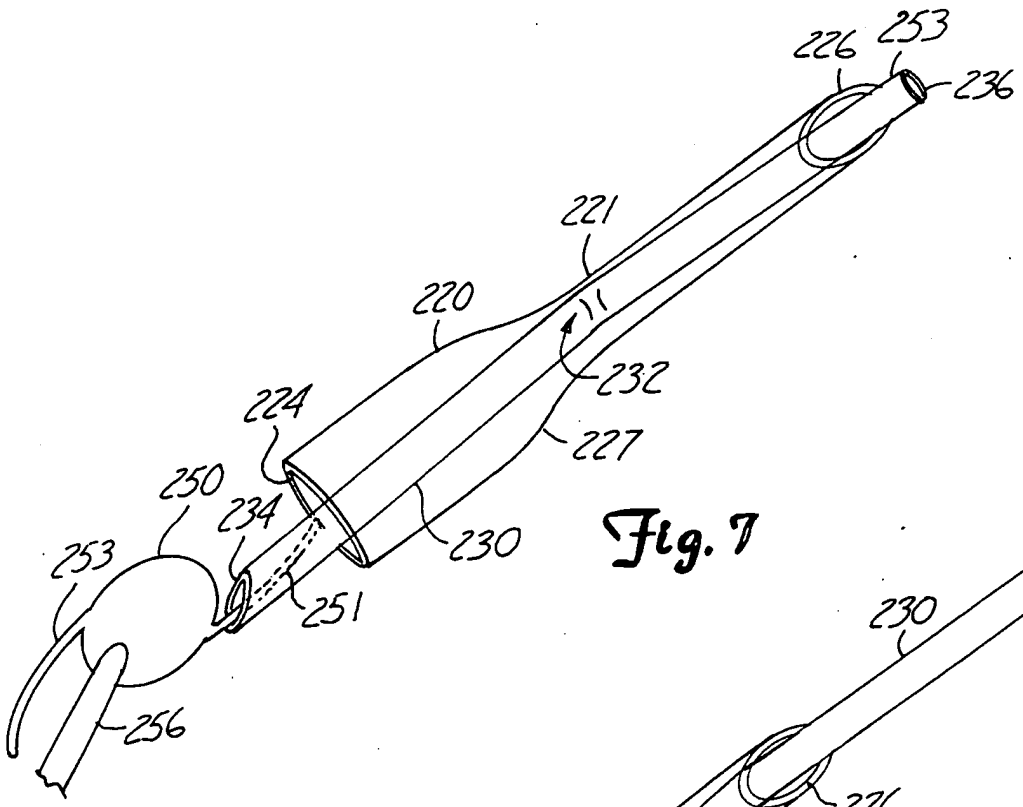

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Fig. 7

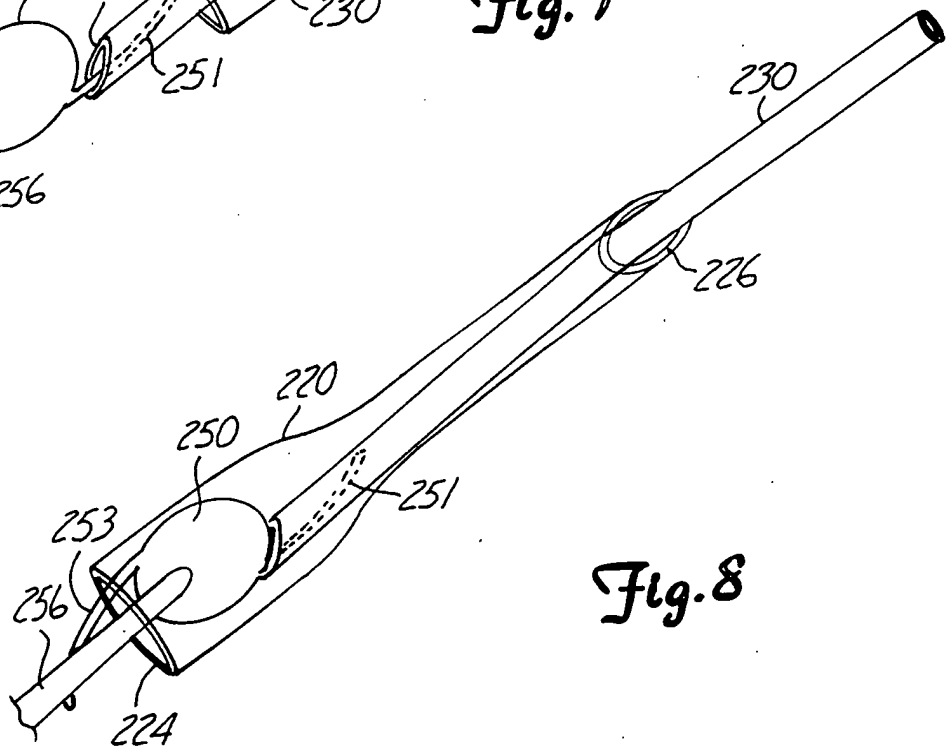
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Fig. 8

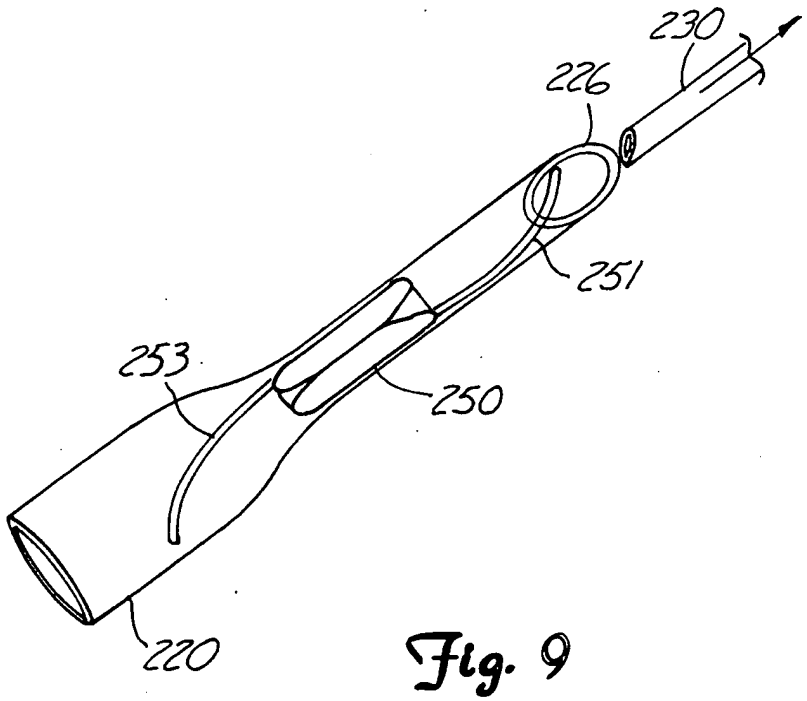

Fig. 9

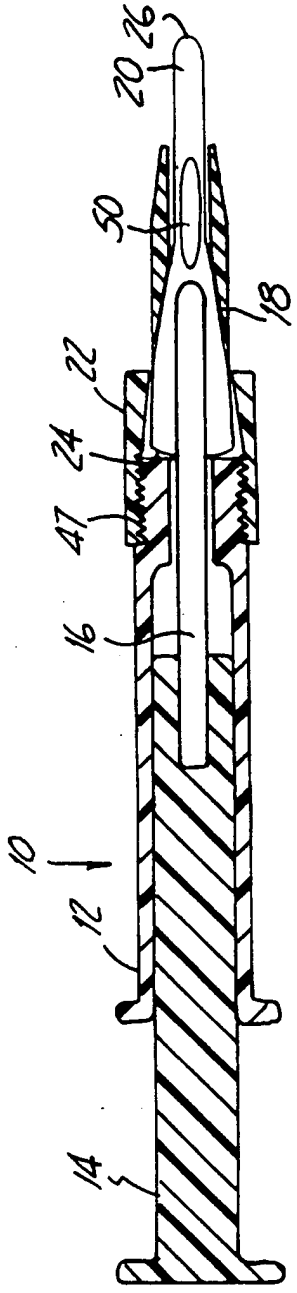

Fig. 10

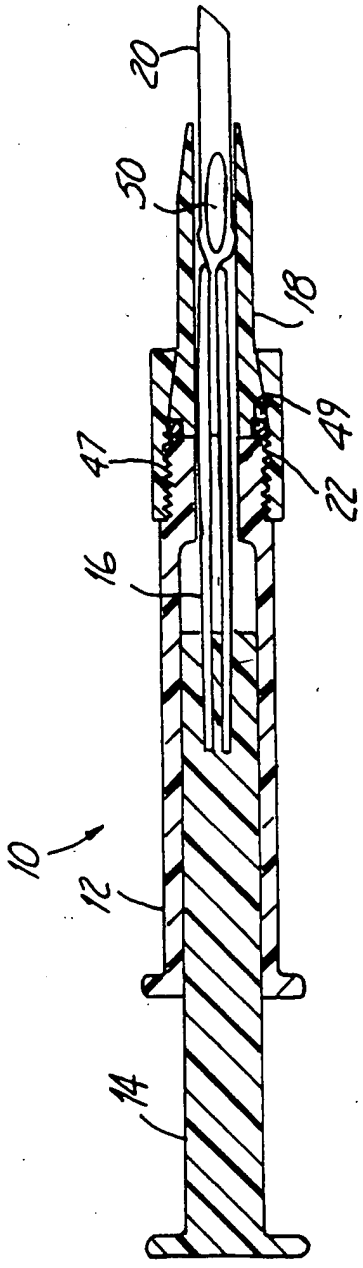

Fig. 11

INTERNATIONAL SEARCH REPORT

Inter. ›nal Application No
PCT/US 98/13759

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 100 410 A (DULEBOHN DAVID H) 31 March 1992 see the whole document ---	1,17,27, 36
A	WO 96 15743 A (FEINGOLD VLADIMIR ;EAGLES DANIEL C (US)) 30 May 1996 see page 10, line 4 - page 11, line 4; figures ---	1,17,27, 36
A	EP 0 340 698 A (ARCOFIL SA) 8 November 1989 see abstract; figures ---	1,17,27, 36
A	US 4 862 885 A (CUMMING J STUART) 5 September 1989 see column 4, line 6 - column 5, line 2; figures -----	1,17,27, 36

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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Date of the actual completion of the international search	Date of mailing of the international search report
6 October 1998	19/10/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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